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01/17/2002

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04/07/2005

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EXAMINER

COE, SUSAN D

ART UNIT

PAPER NUMBER

1654

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/046,897
Filing Date: January 17, 2002
Appellant(s): HAAS, GERHARD J.

Walter D. Ames
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed May 19, 2004.

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(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is incorrect. A correct statement of the status of the claims is as follows:

This appeal involves claims 1-8. Appellant is correct in this statement. However, appellant states that only these claims are pending. Claims 9-14 are still pending but withdrawn from consideration as being drawn to a non-elected invention.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

Appellant states that claims 1-8 stand or fall together.

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(8) Claims Appealed

A substantially correct copy of appealed claim 4 appears on page 1 of the Appendix to the appellant's brief. The minor errors are as follows: the word "humulone" is missing from the end of the claim.

(9) Prior Art of Record

Japanese Patent Application Number 01172332 A (1989).

5,370,863	BARNEY et al.	12-1994
4,170,638	OWADES	10-1979

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-8 stand finally rejected under 35 U.S.C. 103(a) as being unpatentable over Japanese Pat. Appl. No. 01172332 A for the reasons set forth in the Office action of April 8, 2003.

Appellant's claims are directed to a method for sanitizing the udders and teats of dairy cows. The method comprises washing or dipping the udders or teats with an aqueous hops solution in a concentration effective to kill pathogens on the udders or teats.

JP '332 teaches a method for treating mastitis in cows using a water based extract of a solution comprising hops (*Humulus lupulus*) (see page 1 of the English translation submitted September 3, 2002). Mastitis is an infection of the udder and teats of cows and is caused by the pathogen *Staphylococcus aureus*. The reference specifically teaches that the hops containing solution can be in the form of a dispersion (see page 5, fourth full paragraph of English translation). The reference specifically teaches that the hops containing solution can be

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administered through the skin (see page 6, fourth full paragraph of English translation). Thus, JP '332 teaches a method of killing pathogens by applying an aqueous hops solution to the skin of cows. The reference does not specifically teach washing or dipping the udders and teats with this solution. However, a person of ordinary skill in the art would reasonably expect that the active hops containing solution should be administered to the skin at the site of the infection, specifically the skin of the udders and teats. Applying the active hops containing solution to the infected site would clearly involve a washing or dipping means of application. Thus, it is clearly within the skill of one of ordinary skill in the art to expand the teaching of JP '332 of skin application of hops containing solution to include washing and dipping of the infected site. Therefore, an artisan of ordinary skill would be motivated to modify the teaching of JP '332 to include washing and dipping the infected teats of cows to kill pathogens using the hops solution taught by the reference.

Claims 1-8 stand finally rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 4,170,638 in view of Japanese Pat. Appl. No. 01172332 A for the reasons set forth in the Office action of April 8, 2003.

US '638 teaches using a topical aqueous hops extract to inhibit the growth *S. aureus* (see column 1, lines 49-60). US '638 does not specifically teach using the hops extract to sanitize the teats and udders of cows. However, JP '332 teaches that *S. aureus* is the causative agent of bovine mastitis. Therefore, since the hops extract of US '638 is taught to be topically active against *S. aureus*, a person of ordinary skill in the art would reasonably expect that the extract of US '638 would be useful in sanitizing the teats and udders of cows. Thus, based on the teachings

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of the references, a person of ordinary skill in the art would be motivated to use the hops extract of US '638 to sanitize the teats and udders of cows.

US '638 and JP '332 taken together teach using a topical hops composition to sanitize the teats and udders of cows. The references do not specifically teach washing or dipping the teats and udders to apply the compositions. However, applying this active solution to the infected site would clearly involve washing or dipping as an obvious means for applying a transdermally active substance.

Claims 1-7 stand finally rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,370,863 in view of Japanese Pat. Appl. No. 01172332 A for the reasons set forth in the Office action of April 8, 2003.

US '863 teaches that various hops acids have topical antibacterial activity (see column 1, lines 44-52). US '863 teaches that tetrahydroisohumulone and other iso forms of humulone and lupulone function against *S. aureus* (see Table 1).

US '863 does not specifically teach using the hops extract to sanitize the teats and udders of cows. However, JP '332 teaches that *S. aureus* is the causative agent of bovine mastitis. Therefore, since the hops extract of US '863 is taught to be topically active against *S. aureus*, a person of ordinary skill in the art would reasonably expect that the hops acids of US '863 would be useful in sanitizing the teats and udders of cows. Thus, based on the teachings of the references, a person of ordinary skill in the art would be motivated to use the hops extract of US '863 to sanitize the teats and udders of cows.

US '863 and JP '332 taken together teach using a topical hops composition to sanitize the teats and udders of cows. The references do not specifically teach washing or dipping the teats

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and udders to apply the compositions. However, applying this active solution to the infected site would clearly involve washing or dipping as an obvious means for applying a transdermally active substance.

(11) Response to Argument

Regarding the 103(a) rejection based solely of Japanese Pat. Appl. No. 01172332 A, the appellant argues that the examiner is constructing her own claim by stating that JP '332 provides motivation for administering hops extract directly to the udders and teats to treat mastitis.

Appellant argues that the claim is directed to sanitizing the teats and udders of cows using hops not to administering hops to treat mastitis. The appellant argues that the reference does not teach washing or dipping. The appellant also argues that the reference teaches applying the hops extract transdermally but that transdermally "is used interchangeably with transcutaneous. It means 'through the skin.' Example of transdermal administration would be by syringe injection or the use of a medical patch (page 4, first paragraph of the Appeal Brief)." The appellant argues that there is no motivation to "jump" from "a disclosure of a syringe injection" to washing or dipping.

These arguments are not persuasive for the following reasons. The appellant is reading more into the reference than is taught by the reference. The reference as translated states that the hops extract can be applied transdermally or to the skin to treat a pathogenic *Staphylococcus aureus* infection. The reference as translated does not specify that the transdermal administration is performed using a medicated patch or a syringe. In addition, a person of any degree of skill in the pharmaceutical art would appreciate that syringe injection is not transdermal administration. Transdermal administration means that the active substance is absorbed **through** the skin.

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Syringe injection **pierces** the skin; thus, it is not administration through the skin. Thus, the appellants conjecture regarding the teaching of the reference to administer by injection or medicated patch is outside any suggestion of the reference's teaching of transdermal administration.

Furthermore, the reference teaches administering a hops extract to kill the pathogen that causes mastitis in cows. Mastitis is an infection of the udders and teats of cows caused by *S. aureus*. Killing the *S. aureus* sanitizes the udders and teats of the cows using hops extract. Moreover, the appellant's own specification acknowledges that killing the pathogen that causes bovine mastitis falls within their definition of sanitization of the udder and teats of the cows (see paragraph spanning pages 4 and 5). In addition, as discussed above, the reference teaches that the hops extract can be administered through the skin, i.e. transdermally. Based on this statement, a person of ordinary skill in the art would be reasonably expect that the hops extract should be applied to the skin at the site of the infection. The infected site is the udders and teats. Thus, the reference teaches applying the hops extract to the udders and teats of cows to kill the pathogen *S. aureus*. The reference does not specifically teach that this transdermal administration to the udders and teats uses a washing or dipping means. However, washing and dipping is well within the scope of transdermal administration. Applicant's specification does not define washing and dipping using any specific steps. Thus, these limitations are met by rubbing the aqueous hops solution on the infected udders or teats or placing the infected udders or teats in a solution containing the aqueous hops solution. These means of application are clearly means that would be used by an artisan of ordinary skill to administer a transdermal pharmaceutical for sanitizing udders and teats of cows against pathogens.

The appellant also argues that the examiner is disregarding the reference as a whole. The appellant argues that in using the statement that the composition can be transdermally administered that the examiner is “picking and choosing” among the disclosed embodiments of the reference. In addition, the appellant argues that the reference as a whole teaches away from administering the composition transdermally because the preferred embodiment of the reference is oral administration of the hops extract by placing the extract in the food of the cows. The appellant argues that the reference only provides active amounts for this oral administration not for transdermal administration.

However, these arguments are not persuasive. The examiner is not “picking and choosing” to arrive at the appellant’s invention. The reference clearly states that the composition can be administered orally or non-orally. Non-oral administration can be transdermal administration. There are a total of six suggested administration means. Selection of one amongst six is not overly selective. In addition, a person of ordinary skill in the art would clearly possess enough skill to determine an effective amount of the hops extract to administer transdermally. Thus, the reference is still considered to provide motivation for administering the hops extract transdermally to kill pathogens.

Therefore, for these reasons, the reference is considered to properly teach the claims because it provides motivation to sanitize the udder and teats of cows by washing or dipping the udders and teats of the cows using an aqueous solution of hops in an amount effective to kill pathogens.

Regarding the 103(a) rejection based on US Pat. No. 4,170,638 in view of Japanese Pat. Appl. No. 01172332 A, the appellant argues that this rejection has the disclosure of JP ‘332 as

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the controlling element (see page 2, item 6 and paragraph spanning pages 7 and 8 of the Appeal Brief). However, the rejection is based on the prior art as a whole. In this case, it is the combination of US '638 and JP '332. While the teachings of JP '332 are clearly important to this rejection, a piecemeal analysis of only one reference is not appropriate when the rejection is based on the combination of two references.

The appellant also argues that JP '332 does not teach washing or dipping the udder of cows to sanitize the udder or teats and argues that US '638 does not provide any motivation to do so. Furthermore, the appellant argues that US '638 and JP '332 are non-analogous art because US '638 teaches a deodorant that inhibits the growth of *S. aureus* while JP '332 does not teach deodorants. However, the references are considered analogous art because both references are concerned with the same problem, topical control of *S. aureus*. US '638 teaches that hops extracts can be applied topically to control *S. aureus*. This is clearly the same subject matter that is key in JP '332, the control of *S. aureus*. Taking the references together, US '638 teaches that *S. aureus* can be controlled by administering a topical solution of hops extract to a site that contains *S. aureus*. JP '332 teaches that *S. aureus* causes infection in the udders and teats of cows. Thus, when combining the teachings of both of these references, they teach administering a hops solution topically to treat *S. aureus* infection of the udders and teats of cows. The references do not teach washing or dipping to apply the topical composition. However, as discussed above, washing and dipping is well within the scope of topical administration. Applicant's specification does not define washing and dipping using any specific steps. Thus, these limitations are met by rubbing the aqueous hops solution on the infected udders or teats or placing the infected udders or teats in a solution containing the aqueous hops solution. These

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means of application are clearly means that would be used an artisan of ordinary skill to administer a transdermal pharmaceutical for sanitizing udders and teats of cows against pathogens.

Regarding the 103(a) rejection based on US Pat. No. 5,370,863 in view of Japanese Pat. Appl. No. 01172332 A, the appellant argues that this rejection has the disclosure of JP '332 as the controlling element (see page 2, item 6 of the Appeal Brief). However, the rejection is based on the prior art as a whole. In this case, it is the combination of US '863 and JP '332. While the teachings of JP '332 are clearly important to this rejection, a piecemeal analysis of only one reference is not appropriate when the rejection is based on the combination of two references.

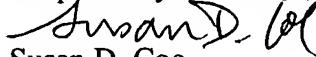
The appellant also argues that the two references are non-analogous prior art because US '863 is drawn to oral care compositions while JP '332 is not drawn to oral care compositions. However, the references are considered analogous art because both references are concerned with the same problem, topical control of *S. aureus*. US '863 teaches that hops extracts can be applied topically to control *S. aureus*. This is clearly the same subject matter that is key in JP '332, the control of *S. aureus*. Taking the references together, US '863 teaches that *S. aureus* can be controlled by administering a topical solution of hops extract to a site that contains *S. aureus*. JP '332 teaches that *S. aureus* caused infection in the udders and teats of cows. Thus, when combining the teachings of both of these references, they teach administering a hops solution topically to treat *S. aureus* infection of the udders and teats of cows. The references do not teach washing or dipping to apply the topical composition. However, as discussed above, washing and dipping is well within the scope of topical administration. Applicant's specification does not define washing and dipping using any specific steps. Thus, these limitations are met by

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rubbing the aqueous hops solution on the infected udders or teats or placing the infected udders or teats in a solution containing the aqueous hops solution. These means of application are clearly means that would be used an artisan of ordinary skill to administer a transdermal pharmaceutical for sanitizing udders and teats of cows against pathogens.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,



Susan D. Coe

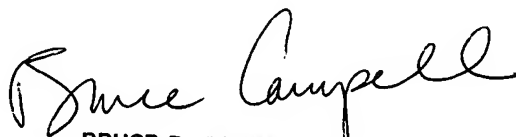
Primary Examiner

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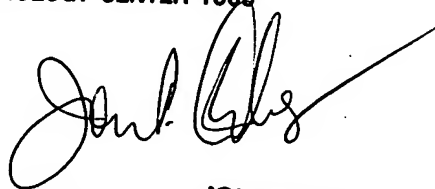
March 28, 2005

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